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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert J. Peach, et al. **Examiner:** Not Yet Known
Serial No.: 09/865,321 **Group Art Unit:** 1646
Filed: May 23, 2001 **Docket No.:** 30436.57USU1
Title: SOLUBLE CTLA4 MUTANT MOLECULES AND USES THEREOF

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on November 4, 2002.


By Tracy Truick

55 South Lake Avenue
Suite 710
Pasadena, California 91101
November 4, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

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SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b) (3))

NOV 20 2002

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This Supplemental Information Disclosure Statement is being filed herewith as a supplement to Applicant's June 19, 2001, Information Disclosure Statement which was submitted under 37 C.F.R. § 1.97 (b)(3) before the mailing of a first Office Action on the merits.

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:

- L104EA29Y (Figure 7, of the subject application) was provided to researchers at Emory University, subject to use restrictions and confidentiality by agreement, more than one year before the priority date of the subject application, i.e. May 26, 2000, for use in animal studies in the U.S.

- L104EA29Y (Figure 7 of the subject application) has been the subject of human clinical trials under the direction and control of Bristol-Myers Squibb Company. L104EA29Y was given to investigators who were involved in the clinical trials subject to use restrictions and confidentiality by agreement. L104EA29Y was administered intravenously to human patients in clinical trials.
- L104EA29Y was first administered intravenously to a human patient as early as November 30, 1998 in Scotland.
- L104EA29Y was first administered intravenously to a human patient as early as April 24, 1999 in the United States.
- A letter dated July 9, 1998 including a report, submitted to the U.S. Food and Drug Administration in connection with an Investigational New Drug (IND) application, is enclosed as Exhibit 171.
 - The letter and report are confidential and were provided confidentially, pursuant to 21 C.F.R. §20.111 or §21 C.F.R. §312.130, to the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration in connection with the Investigational New Drug Application.
 - The enclosed letter and report are redacted versions of what were sent to the U.S. Food and Drug Administration.
 - The report contained the sequence for BMS-224818 (Figure 3 at page 13 of Exhibit 171), which differs from CTLA4Ig at two amino acid residues, Leu₁₀₄-Glu and Ala₂₉-Tyr (Exhibit 171 at page 2).
- An Investigator Brochure dated January 26, 1999 is enclosed as Exhibit 172.
 - The Investigator Brochure is confidential and was provided to investigators who were involved in the clinical trials and subject to confidentiality by agreement, more than one year before the priority date of the subject application, i.e. May 26, 2000.

- The enclosed Investigator Brochure is a redacted version of what was sent to investigators.
- The Investigator Brochure contained a text description and a schematic representation of LEA29Y (Figure 1 at page 6 of Exhibit 172), but not the sequence of L104EA29Y (Figure 7, of the subject application).

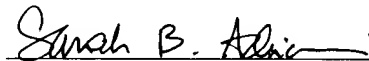
No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the references are not "prior art." Applicants wish to reiterate that the documents and information above were not at the time of filing publicly available since they were provided under confidentiality agreements.

Consideration of the items listed is respectfully requested. Applicants invite the Patent Office to request additional information if necessary. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

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No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,



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FORM 1449*

**INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION**

(Use several sheets if necessary)

Docket Number

30436.57USU1

Application Number

09/865,321

Applicant

Robert J. Peach et al.

Filing Date

May 23, 2001

Group Art Unit

1646

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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		An Investigator Brochure dated January 26, 1999 is enclosed as Exhibit 172 .

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

*Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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May 23, 2001

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DATE CONSIDERED

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